#### **NEVADA STATE BOARD OF PHARMACY**

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

### Automated Drug Dispensing System License Application – For Reproductive Healthcare Centers

Non-Refundable \$500 fee Rev (05/05/2023)

This application cannot be returned by fax or email.

Approval of this application is required for a reproductive healthcare center to use an automated drug dispensing system (System) and maintain a shared inventory in the System to dispense a prescription drug to a patient. A license to use a System is a revocable privilege, and no holder of such a license acquires any vested right therein or thereunder.

An original signature and fee are required to process.

"Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.

A "reproductive healthcare center" means a health care facility owned and operated by a nonprofit corporation or a public health center, as defined in subsection 8 of NRS 449.260, principally engaged in providing family planning services and reproductive health care, including, without limitation, the testing, diagnosis, and treatment of, or providing of medication to prevent sexually transmitted infections or other infections of the urogenital system.

#### **Instructions:**

- 1. Print and mail the completed application to the address indicated above with a <u>non-refundable fee of \$500.00</u> paid for by credit or debit card or a check, cashier's check or money order made payable to the Nevada State Board of Pharmacy. Credit and debit card payments are charged a 5% processing fee.
- 2. Once the completed application with fee is submitted, the System and the proposed location for the System MUST be inspected by a Board inspector before a license may be issued. You will receive an email to schedule your inspection.
- 3. After the System and location receive a satisfactory pre-inspection and the application approved, you will receive your license via email. Please check your spam or junk mail if necessary. The license must be posted on the System so that the license is visible to the public.

#### **Please Note:**

- A separate application and fee are required for each System at a designated location.
- A new application with payment of fee is required for any change in location of a System. A satisfactory inspection of the new location will be required before a new Automated Drug Dispensing System license will be issued and before any dispensing can take place from the new location.
- Controlled substances and compounded drug products are not permitted to be dispensed from a System.
- A System license must be renewed in October of each even numbered year regardless of when the original license was issued. Fees ARE NOT prorated.
- Nevada statutes and regulations can be accessed at www.bop.nv.gov
- For questions contact us at 775-850-1440 or by email at pharmacy@pharmacy.nv.gov.

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# Automated Drug Dispensing System License Application – Reproductive Healthcare Centers Non-Refundable \$500 fee

Rev (05/05/2023)

This application cannot be returned by fax or email. An original signature and fee are required to process.

Section 1: Reproductive Healthcare Center Information			
Facility Name:			
Nevada Business License # (and provide a copy with your app	lication):		
Address:			
City:			
Phone: Fax:	Email:		
Medical Director Name:			
Medical Director Phone #:	Medical Director Email:		
Section 2: Automated Drug Dispensing System (System) Info	rmation		
Name of System:			
Serial #:			
Make:	Model/MFG #:		
MFG Name:			
Section 3: List all registered dispensing practitioners that will	Il be dispensing from the automated drug dispensing system in		
which a shared inventory is maintained. (Use a separate pie	ce of paper if additional space is needed.)		
Name:	Dispensing Practitioner Registration #:		
Name:	Dispensing Practitioner Registration #:		
Name:	Dispensing Practitioner Registration #:		
Name:	Dispensing Practitioner Registration #:		
Name:	Dispensing Practitioner Registration #:		
Name:	Dispensing Practitioner Registration #:		
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Name:	Dispensing Practitioner Registration #:		
Name:	Dispensing Practitioner Registration #:		
Name:			

## Section 4: Laws pertaining to the use of an automated drug dispensing system by a reproductive healthcare center. By signing this application, you attest you have read and understand the components in this section.

- 1. The automated drug dispensing system must conform to all of the following provisions:
  - a. The system must contain only dangerous drugs, excluding compound drug products, for treatment in reproductive health care:
    - i. Approved for use in the system by a dispensing practitioner; and
    - ii. For which the prescription has been processed, verified, and completed in the same manner as a prescription for drugs that are delivered manually by a dispensing practitioner pursuant to NAC 639.742 and 639.745, except that the requirements of paragraph (e) of subsection 3 of NAC 639.742 do not apply.
  - b. The system must:
    - i. Control and track access to the system for stocking, cleaning, maintenance, or any other purpose to ensure that access to the system can be obtained only by a dispensing practitioner practicing at the reproductive healthcare center.
    - ii. Be secure from unauthorized access to and removal of prescription drugs.
    - iii. Be owned or leased by the reproductive healthcare center that obtained the license for the system and operated under the supervision and control of that reproductive healthcare center.
    - iv. Monitor the temperature of the system or be able to have a device installed to monitor the temperature of the system. Such monitoring must include, without limitation, an alarm that records when the temperature of the system reaches a level outside the range compatible with the proper storage of a prescription drug and a method to notify the reproductive healthcare center of the temperature change.
    - v. Create and maintain a complete, accurate and readily retrievable record of all transactions. The record must include, without limitation:
      - 1. The name, strength, quantity and form of dosage of each prescription drug stocked, inventoried, removed or dispensed from the system;
      - 2. Each day and time the system is accessed;
      - 3. An inventory of the prescription drugs stored in the system; and
      - 4. The identity of each person who accesses the system.
    - vi. Authorize access only to patients who previously have indicated to the dispensing practitioner who prescribed the drug their desire to have their prescription drugs dispensed by the system.
    - vii. Provide a method to identify the patient and dispense a prescription drug only to the patient or to an authorized agent of the patient.
    - viii. Dispense one, any combination or all of the prescription drugs available to a patient at the option of the patient at the time that the patient removes the prescription drugs from the system.
    - ix. Record the date and time that the patient removes the prescription drugs from the system.
    - x. Inform a patient:
      - 1. If the patient is using the system at the time that the reproductive healthcare center is open, that the patient may discuss questions and concerns regarding the prescription drug with the dispensing practitioner in person, if available, or through the user-based access technology described in subparagraph (13).
      - 2. If the patient is using the system at the time that the reproductive healthcare center is closed, that the patient may discuss questions and concerns regarding the prescription drug through the user-based access technology described in subparagraph (13).
      - 3. That the patient may choose not to purchase the prescription drug from the system at any time before the system dispenses the prescription drug.
    - xi. Dispense all prescription drugs in containers labeled in conformance with NRS 639.2801.
    - xii. Be installed in such a place and manner that a person is unable to remove the system from its location or obtain access to the system without authorization. The system must be monitored by real-time audio-visual technology or audio-visual recording technology.
    - xiii. Be equipped with user-based access technology that includes, without limitation, an audio-visual function that allows the patient to communicate, in real time, with a dispensing practitioner who has access to any patient record necessary for counseling the patient in compliance with NAC 639.707 and NAC 639.708.
- 2. A reproductive healthcare center that dispenses prescription drugs by an automated drug dispensing system pursuant to this section shall maintain a written policy that sets forth:
  - a. The duties of all persons who are authorized to access the system; and
  - b. The procedures for:

- i. Maintaining the security of the prescription drugs stored in the system during the maintenance and repair of the system;
- ii. The preparation of an inventory of the prescription drugs stored in the system; and
- iii. Stocking the system with prescription drugs.
- 3. A dispensing practitioner practicing at a reproductive healthcare center that dispenses prescription drugs through an automated drug dispensing system pursuant to this section shall comply with all applicable federal and state recordkeeping requirements and shall maintain those records in a readily retrievable manner separate from other medical records.
- 4. Prescription drugs stored in an automated drug dispensing system pursuant to this section shall be deemed part of the inventory and the responsibility of each dispensing practitioner that uses the automated drug dispensing system at the reproductive healthcare center that holds a license for the system. Prescription drugs dispensed from the system shall be deemed to have been dispensed by that dispensing practitioner or those dispensing practitioners, as applicable.
- 5. The Board may prohibit a reproductive healthcare center from using an automated drug dispensing system to furnish a prescription drug to a patient if the Board determines that the system, or one or more dispensing practitioners' use of the system, does not comply with the law.
- 6. The provisions of this section do not prohibit the use of an automated drug dispensing system to furnish a drug or device that is approved by the Food and Drug Administration for sale over the counter without a prescription if the reproductive healthcare center using the system is otherwise authorized to use the system pursuant to the law.
- 7. If a license is issued for the automated drug dispensing system, the license must be posted on the system so that the license is visible to the public.
- 8. As used in this section:
  - a. "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.
  - b. "User-based access technology" means software or hardware that restricts access to an automated drug dispensing system to authorized users by requiring two-factor authentication. Authentication factors may include, without limitation, knowledge, hardware tokens or biometric information.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Medical Director	Print Name (First, Last)		
Medical Director	Original Signature (electronic, cop	pies or stamps not accepted)	Date
	-i		



Applicant Name:

Billing Address:

### NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521
(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444
• Web Page: bop.nv.gov

Payment: Pay application fee by providing your credit or debit card information below, or by submitting a check made payable to Nevada State Board of Pharmacy.  Credit Cards are charged a 5% processing fee			
□ Visa □ MasterCard			
☐ Discover ☐ American Express			
<b>Expiration Date</b> :	CVV (3 digits on back of card):	License Amount:	
/ (MM/YY		\$	
Name on Card:	•		